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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,430	12/09/97	WALKER J	U011415-0

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EXAMINER	
SWARTZ,R	

ART UNIT	PAPER NUMBER
1645	25

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/913,430	Applicant(s) Walker et al
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *29January2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *53-59, 67, 70-72, and 75-94* is/are pending in the application.

4a) Of the above, claim(s) *53-59, 67, and 70-72* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *75-94* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *53-59, 67, 70-72, and 75-94* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 22

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on 29January2001 has been entered.

2. Applicants' Preliminary Amendment, received 29January2001, paper#24, is acknowledged. Claim 76 has been amended.

3. Currently, claims 53-59, 67, 70-72, and 75-94 are pending. Claims 53-59, 67, and 70-72 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention (Office Action, paper#17, 24November1999).

4. Claims 75-94 are under consideration.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 86, 87 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaller et al (U.S. Pat. No. 4,894,332).

The rejected claims are drawn to synthetic antigens produced using DNA sequences coding for *Mycoplasma hyopneumoniae* antigens and methods of producing such antigens. The methods steps recite the use of an antibody to detect said antigens.

Schaller et al teach synthetic antigens and methods of producing such synthetic antigens using DNA sequences coding for *Mycoplasma hyopneumoniae* antigens and detection of said antigens using antibodies (Abstract; col. 1, line 36-44; Fig. 6; Fig. 9).

Applicants argue that Schaller et al do not show or suggest a method using antibodies generated according to step (I) to (iv) of claim 86 in order to identify antigens which have a higher immunological relevance for use in vaccines and diagnostics..

The examiner has considered applicants' arguments, but does not find it persuasive. Claim 86 is drawn to a method for preparing synthetic polypeptides comprising providing an antibody probe "including at least one antibody" produced by steps (I) to (iv). The term "including at least one antibody" encompasses other antibodies which may not be produced by steps (I) to (iv), and therefore encompasses antibodies as taught by Schaller et al.

7. Claims 75, 76, 84, 85, and 89-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Faulds et al (U.S. Pat. No. 5,252,328).

Applicants argue that Faulds et al use whole *Mycoplasma* and identify only those antigens which are in abundance, while the instant invention comprises a much smaller population of antigens detected by antibodies which arise shortly after a challenge. Applicants argue that the

claimed invention requires that the antigen be prepared by a method wherein the recited biological sample is taken under specific conditions and from sites recited in the claim.

The examiner has considered applicants' arguments, but does not find them persuasive. Claim 75 recites that the isolated antigen is from "a sample of *Mycoplasma*" and does define what is meant by "a sample". Claim 76 recites that the isolated antigen "is identifiable" by antibodies taken from infection or lesion sites, but does not require that the antigen come from such sites. Claim 84 is a method to identify an antigen by providing "a sample of *Mycoplasma*" and isolating the antigen thereafter. Claim 85 is a method of purifying antigens by "providing a crude antigen mixture" and thereafter isolating the purified antigen. Claims 89-92 are compositions or methods of using antigens of claim 76. Thus, contrary to applicants' arguments, there is no requirement that the samples be taken under specific conditions and from sites of infection or lesion, nor that the sample be other than "a crude mixture" or "a sample".

Applicants argue that the claimed antigens are not the same as or similar to the antigens identified by Faulds et al as the molecular weights of the antigens are different.

The examiner has considered applicants' argument, but does not find it persuasive. Claims 75, 84, and 85 do not contain any restriction on the antigen other than it be from *Mycoplasma*.

One of the claimed embodiments of claims 76 and 89-92 is a *Mycoplasma* antigen which has a molecular weight of 60-64 kD. Faulds et al teach a *Mycoplasma hyopneumoniae* antigen having an approximate molecular weight of 64 kDa (col. 6, line 4), (Abstract; Example 2).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "functional equivalent thereof".

Applicants argue that those of skill in the art would understand that the term encompasses other amino acid sequences so long as the protein comprising such other sequences has the same function as the sequence encoded by the recited DNA fragment or as the claimed amino acid sequence.

The examiner has considered applicants' argument, but does not find it persuasive. First, claim 93 is drawn to an amino acid sequence encoded by a DNA fragment "comprising" SEQ ID NO:1. The open language permits any length of additional DNA on either end of SEQ ID NO:1. Therefore, is the "functional equivalency" to SEQ ID NO:1 only, the entire amino acid sequence (comprising the undefined regions), or to the undefined regions only. Likewise, claim 94 is drawn to an amino acid sequence "comprising" SEQ ID NO:2, and therefore is indefinite for the same

reason. Second, how many functions are encompassed by "functional equivalent"? The specification only teaches a few antigenic properties.

11. Claims 77-83 and 89-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected as being dependent upon rejected claims.

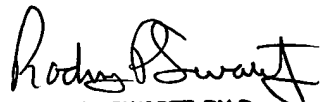
Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

April 23, 2001